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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO |
|--|-----------------|----------------------|---------------------------------|-----------------|
| 09/990,249 | 11/21/2001 | Ing-Ming Chiu | 28489/04000 | 2155 |
| 24024 | 7590 09/09/2003 | | | |
| CALFEE HALTER & GRISWOLD, LLP 800 SUPERIOR AVENUE SUITE 1400 | | | EXAMINER | |
| | | | SHUKLA, RAM R | |
| CLEVELAND, OH 44114 | | , | ART UNIT | PAPER NUMBER |
| | | | 1632 DATE MAILED: 09/09/2003 | |
| | | | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | Application No. | Applicant(s) | | | | |
|--|--|---|--|--|--|--|
| | 09/990,249 | CHIU, ING-MING | | | | |
| Office Action Summary | Examiner | Art Unit | | | | |
| | Ram R. Shukla | 1632 | | | | |
| The MAILING DATE of this communication app Period for Reply | ears on the cover sheet w | ith the correspondence address | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply - If NO period for reply is specified above, the maximum statutory period to Failure to reply within the set or extended period for reply will, by statute, - Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b). Status | 36(a). In no event, however, may a within the statutory minimum of thin will apply and will expire SIX (6) MON, cause the application to become Al | reply be timely filed ty (30) days will be considered timely. NTHS from the mailing date of this communication. BANDONED (35 U.S.C. § 133). | | | | |
| 1) Responsive to communication(s) filed on | • | | | | | |
| 2a) ☐ This action is FINAL . 2b) ☐ Thi | is action is non-final. | | | | | |
| 3) Since this application is in condition for allowat closed in accordance with the practice under a Disposition of Claims | | | | | | |
| 4)⊠ Claim(s) <u>1-36</u> is/are pending in the application | | | | | | |
| 4a) Of the above claim(s) is/are withdrawn from consideration. | | | | | | |
| 5) Claim(s) is/are allowed. | | | | | | |
| 6) Claim(s) is/are rejected. | | | | | | |
| 7) Claim(s) is/are objected to. | | | | | | |
| 8) Claim(s) <u>1-36</u> are subject to restriction and/or e | election requirement. | | | | | |
| Application Papers | | | | | | |
| 9)☐ The specification is objected to by the Examiner. | | | | | | |
| 10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner. | | | | | | |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). | | | | | | |
| 11)☐ The proposed drawing correction filed on is: a)☐ approved b)☐ disapproved by the Examiner. | | | | | | |
| If approved, corrected drawings are required in reply to this Office action. | | | | | | |
| 12) The oath or declaration is objected to by the Examiner. | | | | | | |
| Priority under 35 U.S.C. §§ 119 and 120 | | | | | | |
| 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). | | | | | | |
| a) All b) Some * c) None of: | | | | | | |
| 1. Certified copies of the priority documents have been received. | | | | | | |
| 2. Certified copies of the priority documents have been received in Application No | | | | | | |
| 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. | | | | | | |
| 14) Acknowledgment is made of a claim for domestic | priority under 35 U.S.C. | § 119(e) (to a provisional application). | | | | |
| a) ☐ The translation of the foreign language pro- 15)☐ Acknowledgment is made of a claim for domestic | - • | | | | | |
| Attachment(s) | | | | | | |
| 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) | 5) Notice of | Summary (PTO-413) Paper No(s) nformal Patent Application (PTO-152) | | | | |

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DETAILED ACTION

1. Claims 1-36 are pending.

Election/Restrictions

- 2. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-11, 15-19, drawn to a transgenic mammal comprising a transgene comprising a promoter comprising the nuclear factor binding region of the RR2 cis acting element of an FGF1B promoter, and a DNA fragment comprising a sequence encoding the SV40 large T antigen, classified in class 800, subclass 8.
 - II. Claims 12-14, drawn to a DNA construct comprising a transgene comprising an active portion of the FGF1B promoter operably linked to a DNA fragment encoding the SV40 large T antigen, classified in class 435, subclass 320.1.
 - III. Claims 20-33, drawn to a transgenic mammal comprising a transgene comprising a promoter comprising the nuclear factor binding region of the RR2 cis acting element of an FGF1B promoter, and a reporter gene comprising a sequence encoding an assayable product, classified in class 800, subclass 8.
 - IV. Claims 34-36, drawn to a method of isolating neural stem cells from an animal, classified in class 435, subclass 325.
- 3. The inventions are distinct, each from the other because of the following reasons:

Inventions of the groups I and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP §

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806.04, MPEP § 808.01). In the instant case the different inventions are drawn to transgenic mammals that comprise different transgenes that express different proteins and the mammals will have different characteristics. Additionally, searching the transgenic mammal of group I in the patent and non-patent literature will not yield art relevant to the transgenic mammal of group III.

Inventions of the groups I, II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The invention of the groups I-III are not related because the invention of groups I & III are drawn to transgenic mammals whereas the composition of group II is drawn to a DNA construct. Additionally, the construct of group II differs in structure from the DNA construct used to make the mammal of group I or III.

Inventions of the groups IV are not related to the inventions of groups I-III. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The invention of group IV is drawn to a method whereas the inventions of the group I-III are drawn to compositions. The method of group IV cannot be used to make the compositions of the group I-III. Conversely, the compositions of the groups I-III are not used for practicing the method of groups IV.

4. Because these inventions are distinct for the reasons given above, have acquired a separate status in the art shown by their different classification and their recognized divergent subject matter, and because each invention requires a separate, non-coextensive search, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

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Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ram R. Shukla whose telephone number is (703) 305-1677. The examiner can normally be reached on Monday through Friday from 7:30 am to 4:00 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached on (703) 305-4051. The fax phone number for TC 1600 is (703) 703-872-9306. Any inquiry of a general nature, formal matters or relating to the status of this application or proceeding should be directed to the William Phillips whose telephone number is (703) 305-3413.

RAM R. SHUKLA, PH.D.

Ram R. Shukla, Ph.D. Primary Examiner Art Unit 1632